

PATENT *75*

DOCKET: 506612000104

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Dated: July *22*, 2005 Signature:  (LILIA OLSEN)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Jay WOHLGEMUTH et al.

Serial No.: 10/511,937

Filing Date: April 24, 2003 (PCT/US03/12946)

For:

METHODS AND COMPOSITIONS FOR
DIAGNOSING AND MONITORING
TRANSPLANT REJECTION

Examiner: Not Yet Assigned

Group Art Unit: Not Yet Assigned

**INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98**

MS: PCT/DO/EO/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. Copies of the documents were previously submitted in an Information Disclosure Statement and/or Office Action, directed to the related applications, Serial Number Nos. 10/131,831 filed April 24, 2002 and 10/325,899 filed December 20, 2002, and, accordingly, copies are not included herewith. This

protocol conforms with 37 C.F.R. §1.98(d) and M.P.E.P. 609(A)(2). The Examiner is requested to make these documents of record in the application.

This Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☒ **Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.**
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
 - ☐ A fee is required. A check in the amount of __ is enclosed.
 - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly; no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of __ is enclosed.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist;

(iii) the information, protocols, results and the like reported by third parties are accurate or enabling;
or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing 506612000104. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: July ~~22~~, 2005

Respectfully submitted,

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/511,937
				Filing Date	April 24, 2003
				First Named Inventor	Jay WOHLGEMUTH
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	1	of	16	Attorney Docket Number	506612000104

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
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Examiner Signature		Date Considered	
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Sheet	2	of	16	Attorney Docket Number	506612000104

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Sheet	5	of	16	Attorney Docket Number	506612000104

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Sheet	6	of	16	Attorney Docket Number	506612000104

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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
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*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials ²	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	198.	International Search Report mailed on September 30, 2004, for PCT patent application no. PCT/US03/13015, 4 pages.	

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201.	Akalin, Enver et al. (2001) "Gene Expression Analysis in Human Renal Allograft Biopsy Samples Using High-Density Oligoarray Technology" <i>Transplantation</i> 72 (5): 948-953.
202.	Alizadeh, A. A. et al. (2000) "Distinct types of diffuse large B-cell lymphoma identified by gene expression profiling" <i>Nature</i> 403: 503-11.
203.	Alizadeh, A. et al. (1998) "Probing Lymphocyte Biology by Genomic-Scale Gene Expression Analysis" <i>J. Clin. Immun.</i> 18: 373-379.
204.	Alizadeh, A. et al. (1999) "The Lymphochip: A Specialized cDNA Microarray for the Genomic-scale Analysis of Gene Expression in Normal and Malignant Lymphocytes" <i>Cold Spring Harbor Symposia on Quantitative Biology</i> 54, (New York: Cold Spring Harbor Laboratory Press): 71- 78.
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206.	Arnett, F. C. et al. (1988) "The American Rheumatism Association 1987 revised criteria for the classification of rheumatoid arthritis" <i>Arthritis Rheum</i> 31: 315-24.
207.	Autieri MV, Kelemen S, Thomas BA, Feller ED, Goldman BI, Eisen HJ. (2002) "Allograft inflammatory factor-1 expression correlates with cardiac rejection and development of cardiac allograft vasculopathy" <i>Circulation</i> 106(17):2218-23.
208.	Baechler, Emily C. et al. (2003) "Interferon-inducible gene expression signature in peripheral blood cells of patients with severe lupus" <i>Proc. Natl. Acad. Sci. USA</i> 100 (5): 2610-2615.
209.	Bave, U. (2000) "The combination of apoptotic U937 cells and lupus IgG is a potent IFN-alpha inducer" <i>J. Immunol.</i> 165: 3519-3526.
210.	Bave, U. (2001) "Activation of natural interferon-alpha producing cells by apoptotic U937 cells combined with lupus IgG and its regulation by cytokines" <i>J. Autoimmun.</i> 17: 71-80.

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